RESEARCH PAPER

The Instances and Conditions of Civil Liability of Pharmaceutical Manufacturers in the Civil Law Systems of Iraq, Iran, and the United States of America

AL-Fadhili, Fadhaaa[a], ALFadhili, Mustafa[b]
[a]AL-Rafidain University, Baghdad, Iraq
[b]Tarbiat Modares University, Tehran, Iran

ABSTRACT
Regarding the instances and conditions of civil liability, it may be stated that the existence of three essential elements is required for the establishment of civil liability. These elements include the occurrence of damage, the commission of a harmful act, and the causal relationship between the act and the resulting damage.
Under Iraqi civil law, the civil liability of a pharmacist may arise from errors committed in the course of performing professional duties, provided that the elements of liability—namely fault, damage, and causation—are established.
In Iranian civil law, the civil liability of a pharmacist is similarly based on the fulfillment of three fundamental components: a harmful act, actual damage, and a causal link between the act and the harm incurred.
In U.S. law, pharmacists are typically subject to the same negligence claims as other healthcare professionals, under the tort law framework.
Keywords: Civil liability, pharmacist, Iran, Iraq, United States
How to cite this article: AL-Fadhili F, ALFadhili M. The Instances and Conditions of Civil Liability of Pharmaceutical Manufacturers in the Civil Law Systems of Iraq, Iran, and the United States of America. Int J Drug Deliv Technol. 2026;16(51s): 323-332. DOI: 10.25258/ijddt.16.51s.23
Source of support: Nil.
Conflict of interest: None

Introduction

In Iraqi civil law, the liability of pharmacists holds significant importance and possesses distinctive features. It has attracted the attention of legal scholars and been the subject of in-depth and comprehensive studies, with the aim of enabling the legislator to reformulate legal rules that align with the inherent nature of the law. Damages caused by pharmacists during the prescription of medications and the mechanisms for compensation are currently addressed only through the general rules of civil liability. However, these general provisions fail to comprehensively cover all such damages and do not allow for fair compensation to the injured party or their heirs. Thus, the general rules are inadequate for providing equitable and material compensation to patients.

In the civil law of the United States, pharmacists are often held civilly liable due to negligence. Negligence may be found when a pharmacist owes a duty to the plaintiff, breaches that duty, is the actual and proximate cause of the breach, and the breach results in damage to the plaintiff. The duty is generally defined as acting in a manner consistent with that of a reasonably prudent pharmacist under similar circumstances. Naturally, this definition evolves over time and across jurisdictions, and it is not materially different from that applied to other medical professionals. When pharmacists fail to perform their duties, such failures are frequently characterized as errors.

In Iranian civil law, liability is based on fault. Although the person causing harm is obliged to compensate for the damage, the injured party must prove the fault of the manufacturer or distributor before the court. One of the advantages of this theory is that it does not require the existence of a contractual relationship. Thus, a third party harmed by the use of a drug may bring a claim against the responsible party. Under this system, the injured party must prove two elements: (1) the defect in the drug, and (2) the fault of the manufacturer or distributor in the production or distribution process. However, since proving these two elements is often difficult, this theory fails to adequately protect the consumer.

1. Instances and Conditions of Civil Liability of the Pharmacist in Iraqi Civil Law

The pharmacist's liability, depending on the nature of the fault committed, may be either contractual or tortious. **Contractual liability** arises from a contract and is based on the breach of a pre-existing contractual obligation. Its scope and foundation are determined by the contract itself and whether it includes specific obligations. In contrast, **tortious liability** originates from the law and results from the commission of an unlawful act. It is based on the violation of a fixed legal obligation—namely, the

general duty not to cause harm to others. Therefore, clarifying the nature of the pharmacist's liability is of particular importance, especially considering the pharmacist deals with substances that are distinct in nature from other materials, and this distinction must be accounted for in legal classification (Al-Sanhouri, 2000, p. 105).

The importance of distinguishing between contractual and tortious liability of the pharmacist lies in the fundamental differences between the two types, as the Iraqi Civil Code treats each separately. Contractual liability is governed by provisions relating to contracts, while tortious liability is governed by general rules of extra-contractual responsibility. Despite the common foundation of both types—namely, the breach of a duty, fault, and the obligation to compensate for resulting damages—there are still critical distinctions between them due to differences in their legislative frameworks. These differences are evident in areas such as: excuse (legal justification), legal capacity, amount of compensation, joint liability, and the permissibility of contractual waivers of liability (Belhaj Al-Arabi, 2013, p. 646).

1.1 In Terms of Legal Excuse and Legal Capacity

Civil liability—whether contractual or tortious—differs in terms of excuse and legal capacity. In **contractual liability**, an excuse (legal justification) may be required for the creditor to be entitled to compensation. However, in **tortious liability**, the obligation to compensate arises immediately upon the occurrence of the harmful act, without the need for an excuse on the part of the liable party. This principle is evident in the Iraqi Civil Code, which requires a justification from the debtor in contractual obligations for the creditor to claim damages (Al-Halbousi, 2007, p. 256).

In this context, the term “creditor” refers to the party entitled to performance. If it is proven that the performance has become futile for the creditor, or in the specific cases stated in Article 258 of the Iraqi Civil Code, an exception to the general rule of notification (prior notice) applies in contractual liability. In tortious liability, however, no prior notice to the debtor is required if the obligation arises from harm caused by a wrongful act. In such cases, liability is imposed directly upon the perpetrator without requiring a legal excuse from the injured party, as the legal relationship between the injured party and the wrongdoer arises only after the damage occurs (Khabar Amal, 2003, p. 212).

Regarding **legal capacity**, contractual liability requires that the contracting parties possess full legal competence, such that the responsible party is considered liable only if he or she is of legal age and mentally sound. In contrast, tortious liability (i.e., liability for wrongful acts) does not require full legal capacity; instead, discernment (mental awareness) suffices. This distinction arises because contractual liability is premised on the existence of a valid contract between the responsible party and the injured party, which necessitates full capacity for entering into a legal act. Tortious liability, by contrast, is not based on a contractual relationship but rather on a deviation from proper conduct that mandates a basic capacity to understand the act.

Thus, as Al-Halbousi (2007, p. 258) explains, **tortious liability is broader in scope than contractual liability** with respect to capacity. However, in the case of pharmacist liability, the required capacity is **capacity to act**—which must not be compromised by any defect in will—and not merely capacity to enter into contracts.

1.2 In Terms of Joint Liability

A significant distinction between **contractual liability** and **tortious (negligence-based) liability** arises when multiple parties are jointly responsible for the damage caused, particularly regarding the possibility of holding them **jointly and severally liable**. In cases where damages fall within the realm of contractual liability and involve multiple parties, the general rule is that **no joint and several liability exists among them** unless such liability has been explicitly agreed upon in the contract or is established by law.

To establish joint and several liability in contractual matters, the will of the contracting parties must explicitly support it. This is because a contract is governed by the mutual intent of the parties, and it is this intent that determines whether joint and several liability shall apply. In some cases, the law itself prescribes joint liability among debtors. For example, Article 320 of the Iraqi Civil Code provides that **joint and several liability among debtors is not presumed**, but rather must be based on agreement or statutory provision. If multiple parties are involved in a contractual relationship, **joint and several liability shall not exist unless expressly stipulated in the agreement** (Ahmad Shawqi, 2002, p. 325).

In contrast, when a harmful incident arises outside the scope of contract and causes harm to several individuals, the injured party must pursue compensation from each liable party **in proportion to their share of responsibility**. However, in the realm of tortious liability, the rule is different. **Joint and several liability is mandatory by law** when multiple parties are responsible for a wrongful act. Article 217 of the Iraqi Civil Code explicitly states:

"If several persons are liable for an unlawful act, they shall be jointly and severally liable for compensating the damage caused, whether they are the principal perpetrators or accomplices. The judge shall determine the share of each party in the obligation to pay compensation."

1.3 In Terms of the Extent of Compensation

Compensation within the framework of **contractual liability** is limited to **direct and foreseeable damages** at the time the contract is concluded, provided that the debtor has not committed gross negligence or fraud. If such serious misconduct occurs, the debtor steps outside the bounds of the contractual relationship and is considered to have committed a harmful act that establishes tortious liability. Some legal scholars classify such a debtor as acting in **bad faith**, which necessitates a heightened degree of responsibility (Al-Shawarbeh, 1998, p. 306).

By contrast, in **tortious liability**, the debtor is liable for **all direct damages**, whether foreseeable or not at the time the harmful act occurred. This is because the **source of the obligation is the law itself**, and any breach of it results in tortious liability. The scope of this liability is determined by law alone and is **not subject to the will of the parties**. Accordingly, compensation must cover all direct damages—whether foreseeable or unforeseeable.

For example, if an artist visits a pharmacist to obtain medication to treat a throat condition, and the pharmacist—due to lack of proper professional knowledge—provides medication that causes the artist to lose their voice after consumption, the pharmacist would bear full responsibility for all resulting harm **if the liability is characterized as tortious** (Ali Suleiman, 2005, p. 198). However, **if the liability were classified as contractual**, only the ordinary loss of voice that any typical patient might experience would be eligible for compensation.

1.4 The Nature of Tortious Liability in Relation to Public Order

The provisions of tortious liability are inherently tied to **public order and public morality**, and therefore, **any contractual clause that contravenes these provisions is deemed null and void**. This includes contractual terms that seek to exempt a party from liability or to reduce the extent of such liability. Article 259(3) of the Iraqi Civil Code explicitly states that **any condition contrary to the essence of tortious liability shall be considered invalid**.

In contrast, **contractual liability does not pertain to public order** in the same strict sense. Thus, it is permissible—subject to the absence of fraud or gross negligence on the part of the debtor—for the parties to agree to exemptions from, or reductions of, liability (Al-Faqih, 2002, p. 288).

Modified contracts, which refer to agreements concerning civil liability made **before** the occurrence of harm between the potential tortfeasor and the potentially liable party, are subject to the aforementioned rules. However, **post-damage agreements**, whether in the context of contractual or tortious liability, are generally permissible. These agreements may serve either to **intensify** or to **limit** the legal consequences—whether in whole or in part—of the liability. Such arrangements often take the form of **settlement agreements** between the injured party and the liable party (Mansour, 2006, p. 245).

The Mazot brothers argue that **exemption clauses from liability are impermissible in both contractual and tortious contexts when the damage concerns human safety**, such as in cases involving **medical errors**. This is because the human body cannot be the subject of a contract. Accordingly, a **pharmacist cannot validly agree with a patient to exempt himself from liability** or to **limit his responsibility for damages resulting from a defective drug**.

1.5 In Terms of the Burden of Proof

In cases of contractual liability, the burden of proof lies with the debtor, who must demonstrate that they have fulfilled their contractual obligations to the best of their ability, and that any failure to perform was due to circumstances beyond their control. This is consistent with the provision of Article 168 of the Iraqi Civil Code, which states:

"If performance becomes impossible for a party bound by a contract, he shall be held liable unless he proves that the impossibility was caused by external factors beyond his control."

In contrast, the creditor is only required to prove the existence of the contractual relationship as the source of the obligation. However, in tortious liability, the burden of proof falls on the injured creditor, who must prove that the debtor committed a fault, thereby breaching a legal obligation (Sarwar, 1983, p. 326).

Anyone claiming performance of an obligation must provide evidence for such a claim. Since negligence is the source of tortious liability, it is incumbent upon the creditor to prove the existence of fault. Conversely, a party claiming innocence must provide evidence of performance or present facts demonstrating the extinction of the obligation (Ahmad Al-Saeed, 1993, p. 290).

In contractual liability, the creditor must prove the existence of a binding contract that gives rise to the debtor's obligation, while the debtor may then seek to prove their non-liability. In tortious liability, by

contrast, the source of the obligation is fault, and it is thus the claimant's responsibility to provide evidence of negligence. However, in contractual liability, the obligation to compensate arises directly from the contract, so the claimant is not required to establish fault.

This gives rise to an important legal question: If a pharmacist's conduct meets the conditions for both contractual and tortious liability, may the injured party invoke both types of liability simultaneously, or must they choose one?

The prevailing view is that the combination of both liabilities is impermissible, whether invoked successively or concurrently, as this would unjustly entitle the injured party to double compensation. Therefore, it is not legally acceptable for a claimant to bring claims under both contractual and tortious liability with the intent of obtaining dual compensation. Each liability framework is distinct and governed by separate legal doctrines (Sarwar, 1983, p. 328).

Contractual liability is confined to the scope of the relationship between the contracting parties, whereas tortious liability applies to relationships involving third parties.

As for choosing between the two, opinions vary. Some scholars believe that the creditor has the discretion to select whichever form of liability best serves their interest. Others argue that only contractual liability may be pursued, and that the injured party is barred from bringing a tort claim if a contract exists.

The most plausible and widely supported view, including by legal jurisprudence and the judiciary, is that tortious liability is excluded when a valid contractual relationship exists, since such a contract defines the rights and obligations of the parties. Therefore, the pharmacist should only be held liable under contractual provisions, and where the conditions for both forms of liability are met, the injured party may not rely on tort (Belhaj Al-Arabi, 2013, p. 399). In other words, if a contract exists and the damage suffered results from the pharmacist's failure to perform their contractual duty, then contractual terms govern the dispute, and no additional conditions—outside those stipulated in the contract—may be imposed.

Applying tort principles in such a case would undermine the binding force of contractual provisions, contravening the intention of the legislator who has distinguished between the two systems and accorded each a separate legal framework.

Accordingly, the general rule is that pharmacists' liability for their personal acts arises under contractual liability, and tort liability does not apply unless there is no existing contractual relationship, such as when a pharmacist intervenes to provide emergency medical assistance (Ahmad Al-Saeed, 1993, p. 258).

Upon examining the key differences between contractual and tortious liability, it becomes evident that additional factors also play a role in determining the nature of a pharmacist's liability, particularly because they handle a potentially dangerous product, unlike other professionals. This is especially significant when the harm results from a defective drug.

2. Instances and Conditions of Civil Liability of Pharmacists under Iranian Civil Law

2.1 Fault-Based Liability

Fault-based liability means that the **manufacturer and distributor of a defective drug** are held liable for the damages caused by such a drug. In effect, by producing and distributing a defective pharmaceutical product—and encouraging consumers to purchase it—they become the cause of the harm. According to doctrinal definitions, the "indirect cause" does not directly inflict the damage but contributes to it indirectly through their actions (Fallah, 2021, p. 56).

Since the most critical element of the **causation theory** is the proof of **fault** on the part of the person causing harm, this theory inherits the same limitations found in the **fault-based liability doctrine**. That is, the difficulty in proving fault remains a central challenge.

2.2 Presumption of the Manufacturer's and Distributor's Knowledge of Hidden Defects

Under this theory, **all providers of goods and services** are presumed to have knowledge of any **latent defects** in their products or services. Supplying such goods without appropriate disclosure or warning about these hidden defects constitutes **grounds for liability**. The rationale for compensation is thus grounded in the presumed **malintent** of the supplier. However, this approach faces two primary objections:

1. If the supplier can **prove the absence of malintent**, the presumption is overturned.
2. The **principle of good faith**—which aligns with the **presumption of innocence**—conflicts with the presumption of bad faith.

Moreover, this presumption may only be invoked against **professional suppliers** (Ehsanbakhsh, 2023, p. 169). This line of reasoning is also applicable to pharmaceutical manufacturers and distributors.

However, the potential objection that such suppliers may not be professionals is effectively **moot**, since, according to medical and pharmaceutical regulations, **all drug manufacturers and distributors must meet professional standards**. Specific statutes

outline the **professional requirements** that pharmaceutical production units must satisfy. Therefore, while the objection regarding non-professional status is **irrelevant** in the context of drug suppliers, the **inconsistency of this presumption with the principle of good faith** remains a valid criticism.

2.3 Strict Liability

Strict liability refers to a legal doctrine under which a person may be held liable for damages caused by their product **regardless of fault**. In this form of liability, the injured party is **not required to prove negligence or misconduct** on the part of the supplier. Rather, once a person undertakes the act of supplying a product, they are presumed to have a **duty to ensure its safety** and to bear responsibility for any resulting harm. This applies **irrespective of the existence of a contractual relationship** between the supplier and the injured party, and regardless of whether the injured party was at fault.

In Iranian legal doctrine, **tendencies toward the adoption of strict liability** can be observed. For instance, **Article 2 of the Consumer Protection Act** affirms this approach by placing responsibility on the supplier to guarantee the safety of the product provided (Aminfar, 1995, p. 32).

If an injured **consumer** wishes to seek compensation from a **manufacturer or distributor of pharmaceutical products** under this theory, they must prove two essential elements: First, that the **drug produced or distributed** by the manufacturer or distributor was **defective**; Second, that the **defect in the drug** directly **caused harm** to the claimant (Tabatabaei et al., 2015, p. 60).

It must also be emphasized that **individuals who suffer harm incidentally or accidentally** as a result of consuming a pharmaceutical product may also initiate claims under the doctrine of strict liability against the **manufacturer and distributor**.

This approach thus shifts the burden of ensuring product safety onto the entities involved in the **production and distribution of pharmaceuticals**, recognizing the inherently hazardous nature of such products and the special duty imposed on those who introduce them into the stream of commerce.

2.4 The Duty to Warn as a Form of Non-Contractual Liability

In many cases, **there exists no contractual relationship** between the consumer and the manufacturer or distributor of a pharmaceutical product that would allow for the **duty to warn** to be construed as an **implied contractual obligation**. Nevertheless, pharmaceutical manufacturers and distributors are **legally obligated** to appropriately and reliably inform all individuals who may be exposed to **risks arising from improper use** of the medication or **adverse side effects**. Failure to provide such warnings constitutes **negligence**, and the responsible party shall be held **liable**. The **end user** has the right to claim compensation from the manufacturer and distributor for damages suffered as a result of **lack of adequate guidance or warnings**.

Where no contract exists between the parties, the resulting liability due to failure to inform or warn is based on the **principle of tortious liability (extra-contractual liability)**. In essence, the manufacturer, by **withholding sufficient information or warnings**, has created a situation whereby the consumer suffers harm. Consequently, the manufacturer is deemed liable under the principles of **fault and causation**, and the injured party must prove the manufacturer's negligence. However, under the **strict liability regime**, no proof of fault would be required. In such cases, the mere occurrence of harm and its **causal connection** to the drug suffices to impose liability. The determination of whether the warning or guidance was adequate is left to the **discretion of the judge** (Ehsanbakhsh & Babaei, 2016, p. 102).

Based on the foregoing, it may be concluded that in the modern legal context, the most effective means of protecting pharmaceutical consumers is to adopt the theory of **strict liability** for manufacturers and distributors. Unlike other liability theories, strict liability does **not suffer from the same evidentiary burdens**. Under this theory, pharmaceutical products must be manufactured and distributed in such a way that the consumer can use them **without being exposed to abnormal risks**.

The duties and responsibilities of pharmaceutical manufacturers and distributors under this theory have a **statutory foundation**. The injured consumer must demonstrate a **causal link** between the harm suffered and a **defect in the drug**, as the damage may result from multiple factors—such as defects in both the manufacturing and distribution stages—or because the actual source of the harm lies among several potential parties and **cannot be specifically identified** by the injured party. Thus, adopting **joint and several strict liability** for all pharmaceutical manufacturers and distributors appears to be a fair and efficient solution, as it **relieves the consumer from the burden of proof** and strengthens the protection of their rights.

In cases involving **multiple suppliers**, the best method to safeguard the consumer’s rights is to establish a presumption of causation among all potential suppliers. It is sufficient to show that the harm occurred, that it was caused by a defective or dangerous product, and that **a causal relationship exists** with one or more of the suppliers. The burden then shifts to the suppliers to prove that **they were**

not involved in the creation of the harm. Upon acceptance of this theory, the injured party may file a claim against **any one** of the manufacturers or distributors. The defendant, in turn, retains the right of recourse against the **actual responsible party**, since it is possible, for example, that a claim is brought against a seller who played **no actual role** in the harmful event (Rasouli, 2023, p. 99).

Although Iranian legal history lacks an established precedent for **strict liability**, current realities **necessitate its adoption**. It is important to note that under this theory, **the basis of liability is the defect or danger inherent in the drug**, not the fault or wrongful act of the manufacturer or distributor. The defect giving rise to liability must have been present during the **development, production, or distribution** of the pharmaceutical product (Fallah, 2021, p. 87).

Furthermore, the recognition of strict liability for pharmaceutical suppliers **does not imply absolute submission** to the claims of injured parties, nor does it **eliminate the right to defense**. Manufacturers and distributors **retain the right** to prove the **safety of their product** or to demonstrate that the **damage was caused by the consumer's own conduct**, for which they bear **no legal responsibility**.

3. Instances and Conditions of Civil Liability of Pharmacists in U.S. Civil Law

3.1 Negligence in Dispensing the Wrong Medication

According to the most recent edition of the *Pharmacists Mutual Cross-Sectional Study*, the **largest category of claims** brought against pharmacists—comprising **50 percent** of the total—is related to **wrong drug dispensing**. This category also represents the **most dangerous type of potential error**. Since 1990, the proportion of such claims has remained relatively consistent in each edition of the study. The causes of these errors vary significantly in nature.

In one documented case, a pharmacist received a **telephone prescription** for **digoxin** from a physician's office. The pharmacist prepared the prescription label, correctly counted the digoxin pills into the tray, and placed them into a bottle. When he set the bottle beside the completed label, the phone rang again with a prescription request for **warfarin**. The pharmacist proceeded to fill the warfarin prescription in a similar manner. However, somehow, the **labels for the two prescriptions became switched**—resulting in the **warfarin bottle receiving the digoxin label** and being dispensed to the wrong patient.

In other instances, pharmacy **technicians simply picked the wrong bottle** from the shelf and counted the incorrect medication. If a **busy pharmacist fails to notice the error** during verification or does not adequately review the technician's work, the consequences can be severe.

Such errors are frequently attributed to the **misinterpretation of poor handwriting**, which constitutes one of the **most dangerous categories of pharmacist error**. There has been increasing interest in the use of **electronic prescribing systems**, which aim to **eliminate errors stemming from misreading handwritten prescriptions** and to improve the clarity of communication between physicians and pharmacists (Andrews, 2012, p. 12).

Additionally, confusion often arises due to the **similarity of drug names**. For example, prescriptions for **Navane** may be confused with **Norvasc**, **Prilosec** with **Prozac**, or **Lasix** with **Losec**. Notably, the frequent confusion between **Lasix and Losec** led the manufacturer of Losec to change its name to **Prilosec**. Ironically, Prilosec was subsequently confused with Prozac, and the two drugs were mistakenly dispensed interchangeably.

This problem has become so prevalent that the **United States Pharmacopeia (USP)** established a **special committee** to evaluate the **naming of new pharmaceutical products**. A growing body of scientific research is dedicated to understanding and preventing this type of **look-alike/sound-alike drug error**.

Distractions in the pharmacy are another common and practically **unavoidable aspect** of daily operations. Label-switching errors may occur due to the pharmacist **multitasking** or filling **multiple prescriptions for the same patient**. For instance, a patient may be prescribed **Coumadin once daily** and **Lasix twice daily**. If the **labels are inadvertently switched**, and the patient consumes Coumadin **twice daily instead of once**, it could result in **severe hemorrhaging** (Kolker & Pelofsky, 2012, p. 22).

3.2 Inaccurate Dosage Dispensing by the Pharmacist

The **second largest category of pharmacist-related errors** in the United States is **inaccurate dosage dispensing**. A common example involves receiving a prescription for **125 micrograms of digoxin** and mistakenly dispensing **25 micrograms instead**. Depending on the nature of the drug involved, the consequences of selecting an **inappropriate dosage** can be **dangerous** or even **fatal**, particularly with medications that have a **narrow therapeutic index**.

One frequent outcome of dosage errors is **lack of therapeutic effectiveness**. For instance, a **low-dose error in warfarin (Coumadin)** may lead to **thrombosis**, while an **underdose of digoxin** may result in **congestive heart failure**. Special challenges in substantiating such claims arise with drugs that are

available in **multiple dosage strengths**, such as Coumadin and **Synthroid (levothyroxine)**.

There are **two primary mechanisms** by which these errors occur:

1. **Selecting the wrong bottle** during the dispensing process. In such cases, the prescription label may be accurate, but a drug with the **wrong dosage strength** is placed into the bottle.
2. **Incorrectly entering the dosage information** into the computer system when processing a new prescription.

Pharmacists and technicians must remain **vigilant** against such errors and implement appropriate **management protocols** to mitigate the associated risks. Even **familiar and routinely prescribed medications** are susceptible to this type of error (Snow, Joshua, 2012, p. 1030).

Drugs that are frequently prescribed **casually or routinely** are more prone to dosage-related errors. For example, **Haldol (haloperidol)** is often prescribed for **senile dementia**. However, prescribing **5 milligrams of Haldol** for an **elderly outpatient** is uncommon, as the more standard dose is **0.5 milligrams**. Medications with **multiple dosage forms** and those with **high toxicity profiles** present the greatest risk for **dosage errors**.

In such cases—whether involving **overdosing or underdosing**—if the patient suffers **harm, an adverse effect**, or is even **required to visit the emergency room** as a result of the error, these incidents may all give rise to **legal action** against both the **pharmacist** and the **pharmacy** under **U.S. civil liability laws** (Milenkovich, 2011).

3.3 Negligence in Failing to Adhere to Prescription Instructions

This category of error involves **the inaccurate entry of prescription instructions into the pharmacy computer system**. For instance, in one reported claim, a pharmacist entered a new prescription for **oral contraceptive pills** and **mistakenly typed** the instruction: *"Take two tablets daily for nine months."* The patient continued to refill her contraceptive prescription every 15 days without adhering to the erroneous pharmacy instructions, and without following the label provided by the pharmacy.

Such claims often arise from **misdirection in pediatric prescriptions**. Pharmacy technicians and pharmacists must exercise particular vigilance when handling prescriptions for **young children**, especially when the patient is **under six years of age**. Pharmacists must always be aware of the child's age when verifying a prescription. Under U.S. law, the so-called **"Under Six Rule"** mandates that **special attention** be paid to prescriptions issued for children **under the age of six**. If a patient is in this age group, the pharmacist is legally obligated to perform an **enhanced review** of the instructions and diligently search for any potential errors.

Pharmacists should also read the written instructions aloud to the patient or guardian and ask: *"How did your doctor explain that this medicine should be taken?"* The pharmacist can then use **similar wording or phrasing** to verify whether the patient **understands** the intended dosage and usage instructions. However, these **prescription instruction errors** are often cases that necessitate **direct consultation with the prescribing physician**.

Even if a pharmacist is accustomed to interpreting a particular physician's handwriting, **they cannot be expected to read the doctor's mind**. Pharmacists must be resolute in **contacting the physician** when they encounter **ambiguous or confusing prescriptions**, and must not hesitate to **seek clarification** to prevent potential harm (Campbell, 2006, p. 122).

3.4 Failure to Provide Patient Counseling at the Time of Dispensing

A key provision of the **Omnibus Budget Reconciliation Act (OBRA)** mandates that pharmacists must **review all prescriptions prior to dispensing**, including **screening for allergies, drug interactions**, and a range of other potential issues. Although **drug regimen review** may appear to be a relatively new area of responsibility for pharmacists, it was actually **first codified in the professional standards of pharmacy practice**. The **American Pharmacists Association (APhA)**, in collaboration with the **American Association of Colleges of Pharmacy (AACP)**, defined professional practice standards for pharmacists even before OBRA made many of these elements legally binding.

OBRA requires pharmacists to maintain **medication profiles** and to perform **prospective drug use reviews**, including checking for **therapeutic duplications**, allergies, cross-sensitivities, drug-disease contraindications, and other safety-related factors. It took nearly 15 to 20 years, from the development of these safety protocols in the 1970s to the eventual passage of OBRA, for such practices to become standard.

As a result of this regulation, **failure to conduct a meaningful review of a patient's medication regimen** has led to claims and lawsuits alleging **errors of omission**. When pharmacists engage patients in counseling—explaining how to properly use medications, the intended health outcomes, and precautions—they empower patients to participate in ensuring the **safety and efficacy of their treatment**.

Research indicates that when a pharmacist dispenses medication **face-to-face**, **95% of dispensing errors**

can be identified before the patient leaves the pharmacy. **Leading pharmacy chains** have adopted the practice of **providing counseling with every new prescription** as a standard procedure, rather than simply offering the patient the **option** to ask questions.

While OBRA does not strictly require counseling to occur, it does require the pharmacist to **offer** the patient an opportunity for counseling. In cases involving **high-risk medications**, failure to provide appropriate counseling can result in **predictable and serious consequences**. **Inadequate or incomplete counseling**, as well as a **lack of documentation** of such counseling, may indicate that the pharmacist failed to meet the **standard of care**.

It cannot reasonably be expected that patients will understand all of the information contained in the **Patient Package Insert (PPI)** without the guidance of a trained pharmacist (Sammy Almashat, 2010, p. 11).

In one notable case, the **Illinois Supreme Court** reviewed a lawsuit involving **Walmart Pharmacy**, where a patient, who had disclosed to all of her physicians that she had an allergy to **aspirin**, was prescribed **Toradol** following a medical procedure. The patient brought the prescription to Walmart Pharmacy, where she was (appropriately) asked whether she had any drug allergies. As usual, she responded that she was allergic to aspirin. Despite this, the pharmacy filled the Toradol prescription. The patient experienced **anaphylaxis** and required emergency treatment.

When the patient sued Walmart, the insurer and defense counsel **argued vigorously** that the pharmacist had **no legal duty to warn** the patient, claiming that warning about cross-sensitivities was the **physician's responsibility**. However, **precedent in similar cases** has established that pharmacists **do have a duty** to **screen for known cross-allergies**. The standard of care required the pharmacist to contact the physician and inform them of the patient's known **aspirin allergy**.

Given the well-established **cross-sensitivity between aspirin and Toradol**, prescribing Toradol in this case constituted a **contraindication**, and the pharmacist should have recommended an **alternative analgesic** without such risk. At the very least, the pharmacist should have **refused to dispense** the medication due to the clear risk.

In another case, a pharmacist, when dispensing **trazodone**, printed only the **short form** of the Patient Package Insert (PPI) from the pharmacy computer system instead of the **full version**. The short form omitted a critical **USP DI warning** stating that the medication could cause **priapism (prolonged erections)**, and that a physician should be contacted if this adverse effect occurred.

The **standard of care** requires pharmacists to provide **complete and accurate counseling**, which includes printing and distributing the full-length PPI where appropriate. It is crucial that pharmacists not only adhere to **state pharmacy regulations** but also ensure the existence of **prompt and reliable documentation** that counseling was offered or performed—documentation that can later serve as **evidence in legal proceedings** (Milenkovich, 2011).

3.5 Breach of Patient Confidentiality

Failure to maintain patient confidentiality constitutes another rapidly expanding area of **professional liability claims** against pharmacists. These claims typically involve the **pharmacist or pharmacy technician**, but may also include **any staff member** working in the pharmacy or hospital setting.

The **risk of litigation increases significantly** when a breach of confidentiality concerns **sensitive health issues**, such as **mental health conditions**, **sexually transmitted infections (STIs)**, **contraceptive use**, or the **disclosure of prescription records to family members** or other unauthorized individuals.

For example, in one documented case, a **pharmacy technician** was preparing a prescription for an **AIDS medication** and realized that the male patient was being treated for **HIV**. The technician happened to know the patient's son, whose children were friends with the technician's children. Acting on this knowledge, the technician **informed her children not to associate** with the patient's son. When the patient discovered that **his HIV treatment information had been disclosed** by the pharmacy, he filed a **lawsuit for breach of confidentiality** (Snow, Joshua, 2012, p. 1032).

Such cases highlight the **critical legal and ethical duty** imposed upon pharmacists and all pharmacy personnel to **safeguard the privacy** of patients' health information. Unauthorized disclosure of **protected health information (PHI)**—especially in relation to highly stigmatized medical conditions—can result in **civil liability**, professional disciplinary action, and **reputational harm** to both the individual provider and the institution.

Conclusion

In Iranian law, if one seeks to justify the liability of **pharmaceutical manufacturers and distributors** on the basis of **fault**, it is necessary to establish that they failed to exercise due care in the **production**, **distribution**, or **sale** of the pharmaceutical product. For example, if a manufacturer fails to comply with essential **production standards**, such as violating the requirements of **Note 1 of Article 11 of the Law on Medical and Pharmaceutical Regulations and**

Food and Beverage Substances enacted in 1955—which mandates that substances used in the bleaching and coloring of food and pharmaceutical containers must be pure and non-toxic—and instead uses impure coloring agents, they would be held liable for the **damages sustained by the consumer** as a result of using the defective product. Fault, in legal doctrine, represents a **breach of duty**; thus, it is essential to determine **what duty the manufacturer owes**.

The manufacturer or distributor of a drug has a duty to observe all **precautions, safety measures, and legal and technical standards** associated with the preparation, production, and distribution of pharmaceuticals in a way that ensures the product reaches the consumer in a **safe condition**, and does not cause harm.

Under **U.S. civil law**, pharmacists are typically held to the same **standards of negligence** that apply to other professionals under tort law. Pharmacists are expected to adhere to a **standard of care**, generally defined as acting in the manner of a **reasonably prudent pharmacist** with the customary skills and knowledge under similar circumstances. Pharmacists may be held liable for **harm caused by breaches of that standard**, provided that **causation** and **actual damages** are proven.

Furthermore, **U.S. legal doctrine** recognizes the principle of **vicarious liability**, under which **employers may be held responsible** for the actions of their employees. In addition, pharmacists' errors are often reported to **state pharmacy boards** for **disciplinary measures**, which are separate from civil or criminal court proceedings. These **state boards** possess the authority to **suspend, revoke, or place conditions on a pharmacist's license**.

As a result, disciplinary actions against pharmacists—whether civil or criminal—are generally pursued by **state pharmacy boards** upon the filing of a complaint by the injured party. Penalties may include **license suspension or revocation**, **fines**, **mandatory continuing education**, or **professional probation**. Pharmacists often face **civil liability for negligent conduct**, particularly when they owe a duty to the plaintiff, **breach that duty**, are the **actual and proximate cause** of the harm, and **damages result** from the breach.

In **Iraqi civil law**, the **civil liability of pharmacists** may arise from **errors committed in the course of their professional practice**, provided that the three elements of civil liability—**fault**, **damage**, and **causal relationship**—are established. Iraqi law, however, **does not contain specific provisions** governing the liability of pharmacists. In light of this legislative gap, legal scholarship must explore and differentiate the **legal nature of liability** in cases involving the prescription of medication, administration of medical substances, and other errors that may be committed by pharmacists.

Determining the **legal nature of a pharmacist's civil liability** depends, first, on addressing the **preliminary legal question** of the importance of defining that nature and identifying the **factors contributing to it**. Second, it facilitates recognition of the **specific form of liability** applicable to pharmacists based on the type and circumstances of the error committed.

A. Persian

1. Ehsanbakhsh, Gh. (2023). Mas'ooliyat-e Madani-ye Tolidkonandegan va Towzi'konandegan-e Daro [Civil liability of pharmaceutical manufacturers and distributors]. Tehran: Lidoma Negar Publications.
2. Ehsanbakhsh, Gh., & Babaei, D. (2016). Mas'ooliyat-e Madani-ye Tolidkonandegan va Towzi'konandegan-e Daro [Civil liability of pharmaceutical manufacturers and distributors]. Tazeh-haye Hoquqi Journal, 1(1).
3. Aminfar, R. (1995). Mas'ooliyat-e Madani [Civil liability]. Majmoe-ye Maqalat-e Hoquqi, 4(16).
4. Rasouli, S. (2023). Mas'ooliyat-e Madani-ye Tolidkonandegan-e Daro va Mavad-e Behdashti dar Nezam-e Hoquqi-ye Iran va Englis [Civil liability of pharmaceutical and hygienic product manufacturers in Iranian and British legal systems]. Tehran: Arshadan Publications.
5. Tabatabaei, S. M. S., Niazi, A., Niazi, N., & Nazari, N. (2015). Mas'ooliyat-e Madani-ye Pezeshk va Daro-saz dar Saqt-e Pezeshki [Civil liability of physicians and pharmacists in medical abortion]. Medical Law Journal, (34).
6. Fallah, E. (2021). Mas'ooliyat-e Madani-ye Sherkat-haye Darousazi dar Mored-e Darouhaye Ma'yub [Civil liability of pharmaceutical companies regarding defective drugs]. Tehran: Roham Andisheh Publications.

B. Arabic

1. Al-Saeed, A. (1993). Al-Roshita al-Tibbiyya bayna al-Mafhoom al-Qanuni wa al-Mas'ooliyya al-Madaniyya lil-Sayyadali: Dirasah Muqaranah [The prescription between legal concept and pharmacist's civil

liability: A comparative study]. Mansoura: Dar Umm al-Qura.
2. Shawqi, M. A. (2002). Al-Mas'ooliyya al-'Aqdiyya lil-Madyoon al-Muhtaref [Contractual liability of the professional debtor]. Alexandria: Mansha'at al-Ma'arif.
3. Belhaj Al-Arabi. (2013). Al-Mas'ooliyya 'an al-Ashya' Ghayr al-Hayyah fi al-Qanun al-Madani al-Jaza'iri [Liability for inanimate objects in Algerian civil law]. [No publisher, no date].
4. Al-Halbousi, I. A. H. (2007). Al-Khata' al-Mihni wa al-Khata' al-'Adi fi Itar al-Mas'ooliyya al-Tibbiyya: Dirasah Qanuniyya Muqaranah [Professional vs. ordinary fault in medical liability: A comparative legal study]. Beirut: Al-Halabi Legal Publications.
5. Khabar, A. (2003). Al-Mas'ooliyya al-Madaniyya [Civil liability]. Mawsou'at al-Fikr al-Qanuni, (2), Algeria.
6. Sarour, M. S. (1983). Mas'ooliyyat al-Muntij 'an al-Adrar al-Natijah 'an Muntajatihi al-Khatirah [Producer liability for damage caused by dangerous products]. Cairo: Dar al-Fikr al-'Arabi.
7. Al-Sanhouri, A. R. (2000). Al-Wasit fi Sharh al-Qanun al-Madani al-Jadeed: Nazariyyat al-Iltizam bi-Wajh 'Aam – Masadir al-Iltizam [The intermediary in the explanation of the new civil law: The theory of obligation in general – Sources of obligation] (Vol. 2, 3rd ed.). Beirut: Al-Halabi Legal Publications.
8. Al-Shawarbi, A. (1998). Mas'ooliyyat al-Atibba' wa al-Sayyadilah wa al-Mustashfayat al-Madaniyya wa al-Jina'iyya wa al-Ta'dibiyya [Civil, criminal, and disciplinary liability of doctors, pharmacists, and hospitals]. Alexandria: Mansha'at al-Ma'arif.
9. Ali Suleiman, A. (2005). Al-Nazariyya al-'Aamma lil-Iltizam: Masadir al-Iltizam fi al-Qanun al-Madani al-Jaza'iri [General theory of obligation: Sources of obligation in Algerian civil law] (6th ed.). Algeria: Diwan al-Matboo'at al-Jami'iyya.
10. Al-Faqih, O. I. (2002). Al-Mawsou'ah al-Qanuniyya fi al-Mas'ooliyya al-Madaniyya (Da'wa al-Ta'weez) [Legal encyclopedia on civil liability (Compensation claim)]. Alexandria: Al-Maktab al-Jami'i al-Hadith.
11. Mansour, M. H. (2006). Al-Mas'ooliyya al-Tibbiyya: Al-Tabib al-Jarrah, Tabib al-Asnan, al-Sayyadali, al-'Iyada wa al-Mustashfa wa al-Ahjiza al-Tibbiyya [Medical liability: Surgeon, dentist, pharmacist, clinic, hospital, and medical equipment]. Alexandria: Dar al-Fikr al-Jami'i.

C. Latin

1. Andrews, C.(2012). FDA Guidance Sheds Little Light On Criminal Liability From Park Doctrine Plea. Forbes. February 2, 2011. Accessed on August 21.
2. Campbell, J.(2006). North Carolina Supreme Court Holds That Board of Pharmacy May Regulate Pharmacist Workload Conditions, 33 Rx Ipsa Loquitur, 1, 10.
3. Kolker C. and Pelofsky J. (2012). Reuters. Judge throws out case vs ex-Glaxo lawyer. May 10, 2011. Accessed on July 17.
4. Milenkovich N.(2011), Patient Harm and Pharmacist Liability, 155 Drug Topics 60, 60 Lauren Fleischer, From Pill-Counting to Patient Care: Pharmacists' Standard of Care in Negligence Law.
5. Sammy Almashat, M.D.,(2010). M.P.H, Charles Preston, M.D., M.P.H, Timothy Waterman, B.S., Sidney Wolfe, M.D "Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry:1991 to 2010". Public Citizen's Health Research Group. December 16.
6. Snow, Joshua C.,(2012), "Reducing pharmaceutical fraud: in search of the cocktail prescription" *Public Contract Law Journal* 41. 4: 1027–1046.